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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete If Known</b>	
			Application Number	10/625,870
			Filing Date	July 23, 2003
			First Named Inventor	Howard J. Jacob
			Group Art Unit	
			Examiner Name	
Sheet 1	of 3	Attorney Docket Number	650053.00002	

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Examiner Signature	<i>Klaus Piro</i>	Date Considered	<i>01/26/06</i>
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
J.P.		T. Abe, et al., "Left Ventricular Diastolic Dysfunction in Type 2 Diabetes Mellitus Model Rats," Am. J. Physiol. Hearst Circ. Physiol. 282(1):H138-148, 2002.	
		J. Chen, et al., "Endothelin Receptor Antagonist Combined with a Calcium Channel Blocker Attenuates Renal Injury in Spontaneous Hypertensive Rats with Diabetes," Chin. Med. J. (Engl.) 115(7):972-978, 2002.	
		J.T. Cheng, et al., "Stimulation of Insulin Release in Rats by Die-Huang-Wan, a Herbal Mixture used in Chinese Traditional Medicine," J. Pharm. Pharmacol. 53(2):273-276, 2001.	
		A.M. Cohen, et al., "the Cohen Diabetic (Non-Insulin-Dependent) Hypertensive Rat Model. Description of the Model and Pathologic Findings," Am. J. Hypertens. 6(12):989-995, 1993.	
		Y. Gu, et al., "The Effects of Endothelin Blockade on Renal Expression of Angiotensin II Type 1 Receptor in Diabetic Hypertensive Rats," Zhonghua Yi Xue Za Zhi 82(1):10-13, 2002.	
		S. Hoshi, et al., "Podocyte Injury Promotes Progressive Nephropathy in Zucker Diabetic Fatty Rats," Lab. Invest. 82(1):25-35, 2002.	
		N. Hosomi, et al., "Vascular Proliferation and Transforming Growth Factor-beta Expression in Pre- and Early Stage of Diabetes Mellitus in Otsuka Long-Evans Tokushima Fatty Rats," Atherosclerosis 162(1):69-76, 2002.	
		U. Janssen, et al., "Hypertension Superimposed on Type II Diabetes in Goto Kakizaki Rats Induces Progressive Nephropathy," Kidney Int. 63(6):2162-2170, 2003.	
		S. Jesmin, et al., "Long-acting Calcium Channel Blocker Benidipine Suppresses Expression of Angiogenic Growth Factors and Prevents Cardiac Remodelling in a Type II Diabetic Rat Model," Diabetologia 45(3):402-415, 2002.	
		N. Kanemoto, et al., "Genetic Analysis of Pancreatic Duct Hyperplasia in Otsuka Long-Evans Tokushima Fatty Rats: Possible Association with a Region on Rat Chromosome 14 that includes the Disrupted Cholecystokinin-A Receptor Gene," Pathol. Int. 51(3):133-139, 2001.	
J.P.		P.J. Kaisaki, et al., "Localization, cDNA Sequence and Genomic Organization of the Rat Seipin Gene (Bsc12) and Sequence Analysis in Inbred Rat Models of Type 2 Diabetes Mellitus," Cytogenet. Genome Res. 98(1):71-74, 2002.	

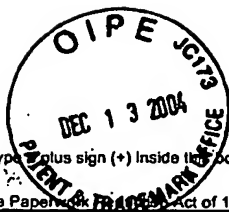
Examiner Signature	<i>Deanna Piro</i>	Date Considered	01/06/06
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I.P.		H. Masuda, "Effects of Temocapril on the Prevention of Early Diabetic Nephropathy in OLETF Rat, an Animal Model for Type 2 Diabetes," Hokkaido Igaku Zasshi 77(5):419-428, 2002.	
		S.A. Mifsud, et al., "Podocyte Foot Process Broadening in Experimental Diabetic Nephropathy: Amelioration with Renin-Angiotensin Blockade," Diabetologia 44(7):878-882, 2001.	
		M. d Aguiar Nobrega, "Distinct Genetic Regulation of the Onset and Progression of Diabetes and Renal Disease in the GOTO-Kakizaki (GK) Rat," pp. 1-275, April, 2001.	
		S.H. Park, et al., "Neointimal Hyperplasia After Arterial Injury is Increased in a Rat Model of Non-insulin-dependent Diabetes Mellitus," Circulation 104(7):815-819, 2001.	
		S.K. Park and S.K. Kang, "Renal Function and Hemodynamic Study in Obese Zucker Rats," Korean J. Intern. Med. 10(1):48-53, 1995.	
		C. Plachot, et al., "Impaired Beta-cell Regeneration After Partial Pancreatectomy in the Adult Goto-Kakizaki Rat, a Spontaneous Model of Type II Diabetes," Histochem. Cell Biol. 116(2):131-139, 2001.	
		P. Serradas, et al., "Fetal Insulin-like Growth Factor-2 Production is Impaired in the GK Rat Model of Type 2 Diabetes," Diabetes 51(2):392-397, 2002.	
		K. Sugimoto, et al., "Renal Protective Effect of YM598, a Selective Endothelin ET(A) Receptor Antagonist, against Diabetic Nephropathy in OLETF Rats," Eur. J. Pharmacol. 450(2):183-189, 2002.	
		Y. Sun, et al., "the Biomimetic [Cr(3)O(2)CCH(2)CH(3)](6)(H(2)O)(3)](+) decreases Plasma Insulin, Cholesterol, and Triglycerides in Healthy and Type II Diabetic Rats but not Type I Diabetic Rats," J. Biol. Inorg. Chem. 7(7-8):852-862, 2002.	
		M.T. Velasque, et al., "Leptin and its Relation to Obesity and Insulin in the SHR/N-corpulent Rat, a Model of Type II Diabetes Mellitus," Int. J. Exp. Diabetes Res. 2(3):217-223, 2001.	
I.P.		S.N. Wang, et al., "Role of Glomerular Ultrafiltration of Growth Factors in Progressive Interstitial Fibrosis in Diabetic Nephropathy," Kidney Int. 57(3):1002-1014, 2000.	

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